APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,495	04/15/2004	Joel Q. Xue	039199-9551-00	8560

7590 11/30/2005	EXAMINER
Joseph D. Kuborn	REIDEL, JESSICA L

ART UNIT	PAPER NUMBER
3766	

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DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	10/825,495	XUE, JOEL Q.
Office Action Summary	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _26 September 2005_.

2a)☐ This action is **FINAL.**   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-23_ is/are pending in the application.

  4a) Of the above claim(s) _16-22_ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-2, 4-7, 9-12, 14-15 and 23_ is/are rejected.

7)☒ Claim(s) _3, 8 and 13_ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _15 April 2004_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

  a)☐ All b)☐ Some * c)☐ None of:

  1.☐ Certified copies of the priority documents have been received.

  2.☐ Certified copies of the priority documents have been received in Application No. _____.

  3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
   Paper No(s)/Mail Date _04/15/04, 09/23/04_.

4) ☐ Interview Summary (PTO-413)
   Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1.   Applicant's election without traverse of Group I, consisting of Claims 1-15 and 23, in the

reply filed on September 26, 2005 is acknowledged. There appears to have been a typographical

error in the reply where Claims 16-18 and 19-23 were "deemed withdrawn". The Examiner is

considering the non-elected Groups II and III, consisting of Claims 16-22 as currently "deemed

withdrawn".

Information Disclosure Statement

2.   The information disclosure statements (IDS) submitted on April 15, 2004 and on

September 23, 2004 have been acknowledged and are being considered by the Examiner.

Claim Rejections - 35 USC § 102

3.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on
> sale in this country, more than one year prior to the date of application for patent in the United States.

4.   Claims 1-2, 7, 9-12, 14-15 and 23 are rejected under 35 U.S.C. 102(b) as being

anticipated by Albrecht et al. (U.S. 5,891,045) (herein Albrecht '045).

5.   As to Claim 1, Albrecht '045 discloses a method of determining alternans data of an ECG

signal (see Albrecht '045 Abstract, column 3, lines 52-67, column 12, lines 23-26 and column

14, lines 45-52). The method of Albrecht '045 comprises, at step 420, determining at least one

parameter, read as a value, representing at least one morphology feature of each beat of the ECG,

generating a set of data points based on a total quantity of values and a total quantity of beats,

(see Albrecht '045 Fig. 9, column 9, lines 33-40, column 10, lines 1-12 and column 13, lines 12-

30) and, at step 425, separating the data points into an array with coordinates corresponding to

the sites of the electrode placements (see Albrecht '045 Fig. 9, column 10, lines 13-16). The

Examiner takes the position that an array implies at least two sets of data points, one versus the

other. The Examiner also takes the position that an "array" is "a rectangular arrangement of

quantities in rows and columns" and that the rows of the array are a first group of data points

determined using a first mathematical function and the columns of the array are a second group

of data points determined using a second mathematical function. Although Albrecht '045 does

not expressly disclose the use of a "mathematical function" to determine the first and second

values, Albrecht '045 does disclose that a parameter may be "computed" (see Albrecht '045

column 10, line 1). The Examiner takes the position that the step of "computing" a parameter

requires the use of a mathematical function.

The method of Albrecht '045 also comprises, at step 430, generating a feature map by

applying a gridding procedure to the array in order to asses the alternans pattern of variation

where the map may be a two-dimensional representation of portions of the body surface (see

Figs. 9, 13 and 18, column 10, lines 49-52 and lines 60-64 and column 11, lines 12-17). The

Examiner takes the position that plotting a first group of points and a second group of points

generates a two-dimensional representation such as Albrecht, each group representing a

parameter, read as a value, calculated at a different electrode location (see Albrecht '045 column

12, lines 53-59). Albrecht '045 further discloses that the feature maps may be used to asses alternans patters of variation and in reference to Fig. 13A a distinct area of abnormal ST segment change is indicated visually by the darker shaded areas 605 (see Albrecht '045 Fig. 13A and column 11, lines 19-21).

6.   As to Claim 2, Albrecht '045 discloses that estimated amplitude of the alternans pattern of variation is determined (see Albrecht '045 column 11, lines 50-54 and column 12, lines 23-28). Specifically, the parameters, read as values, may be variations in the amplitude of the ST segment (see Albrecht '045 Fig. 12 and column 9, lines 35-37).

7.   As to Claim 7, Albrecht '045 discloses that the generated feature map may be an "isometric map, a contour map, a gray scale map, a color map, an isopotential map, or an isochronous map" (see Albrecht '045 column 3, lines 52-60) and in reference to Fig. 13A a distinct area of abnormal ST segment change is indicated visually by the darker shaded areas 605 (see Albrecht '045 Fig. 13A and column 11, lines 19-21).

8.   As to Claim 9, Albrecht '045 discloses that other parameters, read as other values, may include the slope of the ST segment (see Albrecht '045 column 9, lines 52-57). The Examiner takes the position that a calculated "slope" is synonymous to a calculated "difference" between two points on an ECG segment thus values calculated in this manner are calculated via mathematical functions that calculate "difference features".

9.   As to Claims 10-11, Albrecht '045 discloses that when localized ECG signals are obtained for multiple locations on a patient's body, additional diagnostic information may be included in the parameter trend display by mapping the localized ECG signals in X-Y coordinates of a display 135 and that time trends may be presented by displaying a sequence of

such maps (see Albrecht '045 Fig. 19 and column 12, lines 50-60). Albrecht '045 Fig. 19

discloses a sequence of eight maps 1905 and the Examiner takes the position that each sequential

map is a generation of a second set of data points, a third set of data points, a fourth set etc. (see

Albrecht '045 Fig. 19 and column 13, lines 31-37). It is inherent that each Albrecht '045 map is

generated in the same manner as the first map previously described above.

10.   As to Claim 12, the display 1900 allows for visual comparison of each map in the eight

sequential maps 1905 (see Albrecht '045 Fig. 19 and column 13, lines 36-37).

11.   As to Claim 14, Albrecht '045 discloses an alternate embodiment of the methods carried

out by system 100 in which alternans may be detected to indicate electrical instability (see

Albrecht '045 column 14, lines 45-53). It is inherent that the specific alternans that are a direct

indication of electrical instability of a patient are T-wave alternans.

12.   As to Claim 15, Albrecht '045 discloses that other parameters, read as other values, may

be determined that represent non-amplitude based morphology features such as slope of the ST

segment, duration of the T wave or duration of the QRS complex (see Albrecht '045 column 9,

lines 52-57).

13.   As to Claim 23, Albrecht '045 discloses a device 100 for determining alternans data of an

ECG according to the method previously discussed above, comprising an electrode array 105, a

controller 120 including a processor 130, signal conditioning circuitry 125, output device 140

and display 135 (see Albrecht '045 Fig. 1 and column 5, lines 6-23).

14.   Claim 4 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under

35 U.S.C. 103(a) as obvious over Albrecht '045. Albrecht '045 discloses an alternate

embodiment of the methods carried out by system 100 in which alternans may be detected.

Albrecht '045 defines alternans as subtle beat-to-beat changes in the repeating pattern of an ECG

(see Albrecht '045 column 14, lines 45-53). It is inherent, or at least obvious to one having

ordinary skill in the art, that the methods disclosed by Albrecht '045 to determine alternans data

of an ECG, include assigning the data points representing an odd beat to a first group of data

points and assigning the data points representing an even beat to the second group of points in

order to asses beat-to-beat changes in a repeating pattern of an ECG. In addition, Albrecht '045

discloses that values may be computed once during each of a series of epochs, where the epochs

may contain a single representative beat (see Albrecht '045 column 10, lines 1-12).

Claim Rejections - 35 USC § 103

15.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the
> manner in which the invention was made.

16.   Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrecht

'045 in view of Okin et al. (Principal Component Analysis of the T Wave and Prediction of

Cardiovascular Mortality in American Indians. 105 *Circulation* 714 (2002) (herein Okin)).

Albrecht '045 discloses the step of separating the data points into an array with coordinates

corresponding to the sites of the electrode placements (see Albrecht '045 Fig. 9, column 10, lines

13-16). The Examiner takes the position that an "array" is "a rectangular arrangement of

quantities in rows and columns" and is synonymous with a "matrix" due to Applicant's

definition of a "matrix" as "any table of values" and makes reference to page 7, paragraph 42 of

Applicant's disclosure. Albrecht '045 discloses the claimed invention as discussed above except that the method does not include processing the feature matrix using principle component analysis, generating principle component vectors and principle components where the data points correspond to at least one of the principle component vectors.

Okin teaches that principal component analysis is a method for characterizing or mathematically representing data that, when applied to T-waves, derives features of repolarization in a manner that is less dependent on precise determination of T-wave offset (see Okin page 715). Okin also teaches that use of principal component analysis of the T-wave can improve stratification of the risk of cardiovascular death by the ECG. It is inherent that processing a matrix using principle component analysis yields principal component vectors (i.e. eigen vectors) and principal components (i.e. eigen values). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Albrecht, with principal component analysis as taught by Okin, since such a modification would provide improved quantitative variance analysis of T-wave morphologies.

17.   As to Claim 6, it is inherent that taking the square root of the real and imaginary parts of a complex sinusoid (i.e. an ST segment of an ECG signal) will yield the amplitude of that complex sinusoid.

Allowable Subject Matter

18.   Claims 3, 8 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

19.   The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Albrecht et al. (6,047,206) (herein Albrecht '206) discloses an improvement over the previously discussed Albrecht '045 reference that involves stressing the patient.

Ferek-Petrick (U.S. 6,760,615) discloses and implantable medical device adapted for discriminating between tachyarrhythmias using vector analysis.

Kaiser et al. (U.S. 2004/0162498) discloses a method and system for improved measurement of T-wave alternans using ST segment changes and mathematical difference functions.

Xue (U.S. 6,463,320) discloses a method and apparatus for analysis of an ECG via a clinical research workstation that may employ algorithms to evaluate QT dispersion and T-wave alternans. Xue also discloses that the results of the analysis are automatically displayed as a spreadsheet, read as a matrix and that principle component analysis may be used on the data contained in the spreadsheet to describe T wave morphology.

20.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.
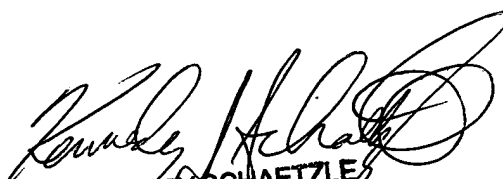
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jessica L. Reidel

KENNEDY SCHAETZLE
PRIMARY EXAMINER
11/27/05